Remarks

Claims 1-84 are pending in this application. Claims 1-84 have been cancelled. New claims 85-92 have been added.

Claims 1-84 have been subjected to a further election requirement. In view of the cancellation of these claims, applicants believe that the further election requirement issued by the Examiner is moot.

Claims 4-10, 14-73 and 80-84 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In view of the cancellation of these claims applicants likewise believe that this rejection is moot.

Claims 1-84 were rejected under either 35 U.S.C. § 102(e), § 102(b) or § 103(a) as being anticipated by or being unpatentable of Yue et al. (US '823), Lee (US '886), Lienhop et al. (US '997) or Allen et al. (US '1410). Applicants submit that these grounds of rejections are moot in view of the cancellation of claims 1-84. New claims 85-92 patentably distinguish over the cited are for the following reasons.

New independent claim 85 recites an oral pharmaceutical solution comprising a quinolone-carboxylic acid antibiotic and a taste masking composition. The taste masking composition comprises from about 0.05 to about 2.5 grams of sucralose per100 ml of the solution, up to about 120 grams of a sugar sweetener per 100 ml of the solution, and at least one flavoring agent. No such solution is taught or suggested by the cited art.

Yue et al. '823 relates to a liquid composition comprising particles of an active medicament spray coated with a taste masking reverse enteric coating. The taste masking coating is formed from a polymer blend of MM/MAE and a cellulose ester in an aqueous vehicle. The enteric coated particles are combined with flavoring agents, sweeteners and other adjuvants as a dry mix for reconstitution as an aqueous suspension. Yue et al. clearly teach that the taste masking is obtained by the enteric coating formed from the polymer blend and not by the adjuvants added to the dry mix. The referenced nowhere even suggests that taste masking could be obtained by a taste-masking composition comprising sucralose, a sugar sweetener and at least one flavoring agent, as taught by the claimed invention.

Lee '886 relates to oral compositions of therapeutic agents that are primarily delivered through the oral mucosal tissue. Lee teaches taste masking compositions for these

therapeutic agents comprising artificial sweeteners and coolants. Lee's objective is to mask the metallic taste often associated with high levels of artificial sweeteners with the use of coolants selected from menthol, WS-3, WS-23, MGA, and the other coolants listed at column 5, lines 1-14 of this reference. The present invention does not relate to therapeutic agents that are intended to be absorbed primarily through the oral mucosal tissue. Moreover, the present invention does not employ coolants in combination with artificial sweeteners to provide taste masking. To the contrary, the present invention provides effective taste masking by combining high levels of the artificial sweetener sucralose with sugar sweeteners and flavoring agents. No such taste masking combination is taught or even suggested by Lee.

Lienhop et al. '997 teach pharmaceutical preparations that include a bitter tasting active agent and a taste masking composition. The taste masking composition comprises sugar derivatives (sorbitol, mannitol, xylitol and mixtures thereof) and hydrogenated maltose syrup. The taste masking composition causes a hyperosmotic condition in the pharmaceutical preparation. According to Lienhop, when such a preparation is administered orally, the hyperosmotic condition in the preparation causes water to move from the taste receptors on the tongue to the liquid in the mouth. The flow of water in this direction is believed to then impede the diffusion of the bitter particles in the preparation towards the taste receptors. See Lienhop at column 4, lines 24-37.

The claimed invention does not utilize a taste masking composition that includes a sugar derivative and hydrogenated maltose, and the claimed invention does not rely on establishing a hyperosmotic condition as taught by Lienhop. As set forth above, the present invention provides taste masking for bitter active agents through the combination of sucralose, a sugar sweetener and at least one flavoring agent. Such a taste masking composition is nowhere taught or even suggested by Lienhop et al.

Allen et al. teach a suspension of trovafloxacin zwitterionic crystals. The suspension includes adjuvants such as suspending agents, thickening agents, and sweetening, buffering and flavoring agents. The objective of the invention is to provide trovaflloxacin in a liquid rather than solid preparation. The reference does not specifically teach taste masking of the antibiotic and certainly does not teach or suggest the taste masking composition recited in the instant claims.

In view of the foregoing, applicants submit that new claims 85-92 patentably distinguish over the cited art and a Notice of Allowance directed to these claims is requested.

Applicants expect to submit a Supplemental Information Disclosure Statement within a few days following the filing of this Response. The Examiner is asked to consider this Response together with the Supplemental IDS that applicants will file shortly.

Applicants hereby petition for a two-month extension of time in order to respond to the outstanding Office Action. Please charge the fee of $420.00 required under 27 C.F.R. § 1.17(a)(2), and any additional fees that may be required, to Deposit Account No. 10-0750/ORT-1587/JSK.

Should there be any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

By: _____
Joseph S. Kentoffio
Reg. No. 33,189
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-3711
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